REMARKS

Restriction Requirement

Applicant elects Group I, Claims 20-27, directed to a flexible implant structure. This Election is made with traverse because, as will be pointed out below, the cited reference of Ogawa does not teach nor suggest the common technical feature in both the product claims and the process claims.

Ogawa has been cited to teach that the features that are common between the product claims and the method claims are not novel. Applicant respectfully disagrees.

First, it should be noted that in Table 1 of Ogawa, he teaches the combination of PLGA (90/10)-21200 in combination with D-Lactide. The only combination of Lactide with the copolymer of PLGA is with respect to the copolymer PLGA having a molecular ratio of lactic acid to glycol acid of 90:10. This can be contrasted against the present Invention where the weight ratio between lactic acid and glycol acid units is 80/20 to 20/80. Thus, the claimed combination of copolymer with the biocompatible

plasticizer, as recited in the claims, is not taught in Ogawa because the copolymer used in Ogawa is outside the claimed range. Thus, from the point of view of novelty/anticipation, Ogawa does not teach the specific combination of a copolymer recited in the claims in combination with the biocompatible plasticizer because the copolymer in Ogawa is outside the copolymer in the recited claims.

Second, the product and the process claims in the present Invention require that the mixture of copolymer and plasticizer have a Tg below or equal to 15°C. Ogawa is completely silent on the Tg of the mixture of copolymer PLGA and D-Lactide. Furthermore, the Examiner has pointed to no support for an inherency argument and, thus, Ogawa also fails to defeat novelty/anticipation because he fails to teach, either specifically or inherently, the Tg as recited in both the product and process claims.

Third, the physical structure of the implant of the claims is different than the physical structure of the microcapsules of Ogawa. As can be seen under the experimental section on page 1503 of Ogawa, the microcapsules have a shell made of the polymer and D-

Lactide which surrounds an interior containing the active ingredient of the leuprolide acetate. This can be seen by the formation of the emulsion which is a water in oil emulsion where the water contains the leuprolide acetate and the oil is the copolymer PLGA and D-Lactide. In contrast, the present Invention has an intimate mixture of the support and the active principle exhibits cohesion between the active principle and the support. Both the product claims and the process claims refer to this cohesion between the active principle and the support. Thus, the structure of the microcapsule of Ogawa is different than the cohesion structure of the claims.

In conclusion, Applicant submits that Ogawa does not defeat novelty on three grounds. First, the combination of D-Lactide with the copolymer PLGA is outside the claims because the copolymer has a different weight ratio of lactic acid to glycolic acid. Second, the combination of PLGA and D-Lactide of Ogawa does not have, either specifically or inherently, the claimed Tg of the claims. Third, the microcapsule has a different structure than the cohesive structure of the active principle and the support recited in the claims.

In view of the foregoing, Applicant traverses the Restriction and vehemently disagrees with the Examiner's position that Ogawa defeats novelty of the recited claims.

In view of the foregoing, it is respectfully submitted that the Application is in condition for examination and reconsideration and examination are respectfully requested.

Should any fees or extensions of time be necessary in order to maintain this Application in pending condition, appropriate requests are hereby made and authorization is given to debit account #02-2275.

Respectfully submitted,

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